REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL

ON

EPA'S PLANNED PROPOSAL OF NATIONAL PRIMARY DRINKING WATER REGULATION FOR RADON

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1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel convened for the proposed rulemaking on the National Primary Drinking Water Regulation for Radon that the Environmental Protection Agency (EPA) is currently developing. On July 9, 1998, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

This report provides background information on the proposed radon in drinking water rule being developed and the types of small entities that would be subject to the proposed rule; a summary of OGWDW's outreach activities; and the comments and recommendations of the small entity representatives (SERs). In addition, Section 609(b) of the RFA directs the review panel to report on the comments of SERs and make findings as to issues related to identified elements of an initial regulatory flexibility analysis (IRFA) under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

Once completed, the Panel report is provided to the agency issuing the proposed rule and included in the rulemaking record. In light of the Panel report, the agency is to make changes, where appropriate, to the draft proposed rule, the IRFA for the proposed rule, or the decision on whether an IRFA is required.

The Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule. The Agency expects additional information will be developed or obtained during the remainder of the rule development process. It is important to note that the Panel makes its report at an early stage in the rule development process when SER comments and insights can inform the Agency's thinking about fundamental issues of rule design and scope, and can be taken into account in a meaningful way. Early involvement ensures that small entity perspectives are considered as the Agency develops the supporting analyses for the rule. However, this early opportunity means that less information and analysis regarding possible regulatory options is available than would be the case at a later stage in the process when the Agency focuses in on a relatively narrow set of regulatory options. For the radon rule, there is an additional opportunity for input in advance of the proposed rule. In addition to several stakeholder forums, small entities and other stakeholders will be able to comment on the Health Risk Reduction and Cost Analysis for various MCL options and EPA will address significant comments in the preamble to the proposed rule.

Any options the Panel identifies for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, protective of public health and consistent with the statute authorizing the proposed rule.

2. BACKGROUND

Radon is a colorless, odorless, naturally occurring gas. Radon comes from the natural decay of uranium, an element found in nearly all soils, and also in rock and water. As the radioactive material in rock or soil decays slowly over time, it produces radon gas. The gas tends to rise towards the ground's surface and infiltrate air or water-filled pores in the soil. Eventually, the soil releases the gas directly to the atmosphere, or ground water transports the radon away from the site where the rock material originally produced it. Wells tapping into sources of naturally occurring radon in ground water then supply that water to every home to which the water is distributed. In common use, the term radon collectively refers both to radon gas (i.e., radon-222) as well as its radioactive decay products, or progeny.

National and international health organizations have established that both radon and its progeny are known to cause cancer in humans. In 1988, the International Agency for Research on Cancer (IARC) convened a panel of world experts that unanimously agreed that there is sufficient evidence to conclude that radon causes cancer in humans and experimental animals. The Biological Effects of Ionizing Radiation (BEIR) Committees, assembled by the National Academy of Sciences (NAS), the International Commission on Radiological Protection (ICRP), and the National Council on Radiation

Protection and Measurement (NCRP), have also reviewed the available data and agreed that radon exposure causes cancer in humans. EPA has concurred with these findings and classified radon as a human carcinogen based on sufficient evidence of cancer in humans.

People are exposed to radon in drinking water through two pathways: inhalation and ingestion. Radon gas can be released into indoor air when water is used for showering and other household uses. Inhalation of radon gas and progeny increases the risk of lung cancer. Some research suggests that swallowing water with elevated radon levels may increase the risk of cancer in the digestive system and other internal organs. Previous assessments by EPA and others indicate that the radon in drinking water increases risk of lung cancer from inhalation and stomach and other internal organ cancers from ingestion. The National Academy of Sciences (NAS) Radon in Drinking Water Committee is writing a report on their assessment of inhalation and ingestion risks pursuant to Section 1412(b)(13)(B) of the Safe Drinking Water Act (SDWA).

2.1 Regulatory History

EPA does not currently regulate radon in drinking water, although the Agency is in the process of developing a regulation to limit the amount of radon in public drinking water supplies, which is the subject of this report. In July 1991, EPA proposed a National Primary Drinking Water Regulation (NPDWR) for radon-222, radium-226, radium-228, uranium, gross alpha emitters, and beta and photon emitters (56 FR 33050). In the 1991 proposal, EPA set a Maximum Contaminant Level (MCL) for radon in drinking water at 300 pCi/L[1] to address public water systems subject to the SDWA (serving 25 or more individuals, or with 15 or more service connections). In 1991, EPA estimated that approximately 27,000 community and non-transient non-community water systems serving 19 million people would exceed the proposed MCL without additional treatment. Those commenting on the 1991 proposal for radon raised several concerns, including cost of implementation, especially for small systems, and the larger risk to public health from radon in indoor air from soil under buildings.

In the 1996 Amendments to the SDWA, Congress established a new charter for public water systems, States, and EPA to protect the safety of public drinking water supplies. Among other mandates, the amendments [Section 1412(b)(13)] direct EPA to propose a Maximum Contaminant Level Goal (MCLG) and NPDWR for radon by August, 1999 and finalize the regulation by August, 2000. In addition, EPA is required to: (1) withdraw the 1991 proposal for radon-222 (withdrawn on August 6, 1997; 62 FR 42221); (2) arrange for the NAS to conduct an independent risk assessment for radon in drinking water (as mentioned above) and an independent assessment of risk reduction benefits from various mitigation measures to reduce radon in indoor air; and (3) publish a radon health risk reduction and cost analysis for possible MCLs for public comment, by February, 1999.

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[1] A Curie (Ci) is a standard measure of radioactivity. A picoCurie (pCi) is one trillionth of a Curie and is equivalent to 0.037 nuclear disintegrations per second.

The NAS report, which is expected to include the unit risk (risk per pCi/L) associated with exposure to radon in drinking water, will be used along with other available information by EPA to develop a national risk estimate for radon in drinking water.

Under the 1996 SDWA Amendments, EPA is to promulgate an alternative MCL (AMCL) and publish guidelines for multi-media mitigation programs to decrease radon levels in air, if the MCL is "more stringent than necessary to reduce the contribution to radon in indoor air from drinking water to a concentration that is equivalent to the national average concentration of radon in outdoor air." The AMCL is to be set at a level which would "result in contribution of radon from drinking water to radon levels in indoor air equivalent to the national average concentration of radon in outdoor air." Therefore, the AMCL level would be linked to the average outdoor radon level and the rate at which radon in drinking water transfers to air (water to air transfer factor). The AMCL is linked to a multi-media mitigation program to address radon in indoor air (see below).

2.2 Related Federal Rules

There are several Federal Rules under development with treatment requirements that may relate to the radon in drinking water rule. The following is a brief description of each rule, as well as the impact the radon in drinking water rule may have on other rules. The radon in drinking water rule is expected to be promulgated in a similar timeframe to the Ground Water Rule, the Arsenic Rule, and the Microbial and Disinfection By-Product Standards, and is not expected to conflict with these rules.

Ground Water Rule (GWR). The goals of the GWR are to: (1) provide a consistent level of public health protection; (2) prevent waterborne microbial disease outbreaks; (3) reduce endemic waterborne disease; and (4) prevent fecal contamination from reaching consumers. EPA has the responsibility to develop a ground water rule which not only specifies the appropriate use of disinfection, but also addresses other components of ground water systems to assure public health protection. This general provision is supplemented with an additional requirement that EPA develop standards specifying the use of disinfectants for ground water systems as necessary. To meet these requirements, EPA is working with stakeholders to develop a GWR proposal by March, 1999 and a final rule by November, 2000.

Systems that are not currently disinfecting may need to disinfect (e.g., using chlorination or ultraviolet light) following aeration treatment or granular activated carbon (GAC) treatment for radon. It may be most efficient for those systems to follow the disinfection guidelines of the GWR, even though the GWR itself will recommend disinfection only as a last resort. Disinfection in accordance with either the radon in drinking water rule or the GWR will satisfy the disinfection requirements of the other rule (i.e., systems affected by both rules will only have to put in disinfection once). For systems without a distribution system (e.g., non-transient non-community water systems), the use of ultraviolet light for disinfection also may be able to handle the needs of both the GWR and the Microbial and Disinfection Byproducts Rule (see below). An advantage of ultraviolet light is that it will not cause disinfectant by-product complications. For community water systems, however, ultraviolet light may not be an attractive disinfection alternative because they would still need chemical addition in order to maintain a residual disinfectant in the water distribution system.

Arsenic. In the 1996 amendments to the SDWA, Congress directed EPA to prepare an arsenic research plan by February, 1997, to study low-level health effects of arsenic and consult with interested entities in carrying out the research. The Act also encourages EPA to enter into cooperative agreements to carry out the studies. Furthermore, EPA must issue a proposed MCLG and NPDWR by January 1, 2000, and issue a final arsenic rule by January 1, 2001 [§1412(b)(12)(A)]. Currently, the arsenic MCL only applies to community water systems, but the new MCL would also apply to non-transient non-community supplies (e.g., schools, office buildings). Because both the radon and arsenic rule will apply to ground water systems, some systems may need to treat for both contaminants. If systems have aeration and disinfection treatments in place as a result of the radon in drinking water rule, they will be less affected by the Arsenic Rule because aeration converts arsenic to a chemical species (arsenic V) that is easier to remove (than arsenic III).

Microbial and Disinfection By-product Standards. To control microbial contamination and disinfection by-products and to strengthen control of microbial pathogens in drinking water, EPA is developing a group of interrelated regulations, as required by SDWA. These standards, referred to collectively as the Microbial and Disinfection By-product (M/DBP) Rules, are intended to address risk trade-offs between the two different types of contaminants.

EPA proposed a Stage 1 Disinfectants/Disinfection By-products Rule (DBPR) and Interim Enhanced Surface Water Treatment Rule (IESWTR) in July 1994, and published Notices of Data Availability (NODAs) for these rules in November 1997. EPA has published (March 31, 1998) another NODA on the Stage 1 DBPR, which provides an additional opportunity for the public to comment on new information since the 1997 NODA. The purpose of the proposed DBPR is to establish drinking water standards that concurrently minimize the risks from microbial pathogens and minimize the risks from disinfectants and disinfection by-products. The proposed IESWTR would provide additional protection against pathogens in drinking water from public water systems that use surface water or ground water under the influence of surface water.

The Agency has finalized and is currently implementing a third rule, the Information Collection Rule, which will provide data to support development of subsequent M/DBP regulations. These subsequent rules include a Stage 2 DBPR and a companion "Long-Term 2" Enhanced Surface Water Treatment Rule (LT2ESWTR).

Systems coming into compliance with the radon regulation will also need to remain in compliance with EPA's Total Coliform Rule (promulgated June, 1989), which remains a cornerstone in protecting distributed water from re-contamination.

Radon treatment (aeration and disinfection treatments) may add a burden under the forthcoming Microbial and Disinfection By-product rules, particularly where DBP precursors (i.e., naturally organic materials) are prevalent in source water. Where DBP precursors are prevalent, there will be a need to alter the disinfection process. Systems may also need to address other EPA rules (e.g., corrosion control, as promulgated in 1991) as these new treatments come on-line.

3. OVERVIEW OF POTENTIAL REQUIREMENTS AND GUIDELINES OF THE PROPOSAL

EPA has not yet developed an MCL or compliance requirements for the proposed rule. It is anticipated that EPA will develop these requirements after review of the NAS report, and consideration of input from States and other stakeholders, including SERs. However, EPA has identified two main categories of potential compliance requirements: (1) treatment; and (2) monitoring. EPA is also developing multi-media mitigation program guidelines to provide regulatory flexibility. These categories of potential requirements and an overview of the multi-media mitigation program guidelines are discussed below.

3.1 Treatment

Before attempting technological solutions to water quality problems, small water supply systems should exhaust other available alternatives for improving water quality. One option is to find another water source, by relocating a well for example. Another option is to purchase water from a nearby utility. Such options are often more cost effective than attempting to use treatment to remove contaminants from poor-quality source water, especially for small systems. The National Research Council (NRC, 1997) recommends that the application of any drinking water treatment technology (other than disinfection) should be considered only after alternatives to treatment are exhausted.

Background. When other options are not available, small water systems may rely on technological solutions to water quality problems. Since small water systems often have difficulties raising the revenue to install and operate water treatment technologies, they often look for low-cost treatment options. For small systems that must treat, several small system-specific strategies exist. In the case of centralized treatment, small systems can reduce their compliance costs by using package plant aerators or using “circuit rider” operators who maintain and monitor operations at more than one small system. Alternatively, point-of-entry (POE) devices that treat water at the point of entry to each household can be more cost-effective than centralized treatment for systems serving 25 to 500 people.

EPA will not require a specific treatment technology for treating radon in drinking water, but will identify the best available treatment technology. EPA also will identify “compliance technologies” that are affordable and otherwise applicable to typical small drinking water systems for meeting the radon MCL or AMCL. Owners and operators may choose any technology or technology variant that best suits their conditions, as long as the MCL or AMCL is met. The traditional, and usually most costly treatment option, involves the installation of new technology at the water treatment plant through site-specific engineering. This option, referred to as "centralized treatment," often requires some degree of pilot testing to demonstrate that the treatment equipment is performing properly. However, as will be discussed, the most applicable treatment for radon in drinking water is "aeration" or "air stripping," which requires less site-specific engineering than many other technologies and does not require extensive pilot testing.

Aeration. Aeration was proposed as the best available treatment technology for radon in the 1991 radionuclides proposal. Aeration treatment involves bringing the raw ground water into contact[2] with air, allowing contaminants to transfer from the water into the air. Radon is readily removed this way, since it greatly "prefers" being in air relative to being dissolved in water. Common aeration technology varieties include "packed tower aeration," "diffused aeration," and "spray aeration." In general, aeration treatment can be installed for a low cost compared to other treatment technologies. The treatment process is highly adaptable to small drinking water systems, often involving a simple retrofit to existing treatment basins and/or the use of "package plant[3] aerators." Aeration systems are generally set for automatic operation, are not labor intensive, and do not call for the addition of chemicals (pre- and post-treatment may require chemical addition). Daily maintenance is required only to ensure that the equipment is working and to provide preventive maintenance. Costs and treatment efficiency, however, both increase with increasing equipment complexity. If contaminant concentrations are high and regulations require permitting and off-gas treatment or other significant engineering controls, this may also cause costs to increase significantly.

There are many small water systems currently using aeration treatment to treat for radon, volatile organic chemicals, hydrogen sulfide, and excess carbon dioxide. Current estimates indicate that around 20 percent of ground water systems serving 500 to 10,000 persons already aerate their water, while approximately seven percent of ground water systems serving between 100 to 500 persons use aeration technology. Only around one percent of the smallest ground water systems (those serving 25 to 100 persons) are currently aerating (USEPA, 1997).

In 1994, average small system costs for aeration were estimated to range from approximately $220 per household per year ($$/HH/YR) for systems serving 25 to 100 people to approximately

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[2] The contact surface area is increased through a variety of engineering means, but the general idea is that the raw water and air are vigorously mixed together to the degree necessary to replace the radon with air. The air mixed with the contaminant, or the "off-gas," is then piped out of the treatment plant to be diluted with outdoor air. In some cases, the off-gas must be treated to remove contaminants or the off-gas system must be designed to maximize dilution with outdoor air before the off-gas is released to the environment.

[3] A package plant is a pre-engineered "off-the-shelf" unit that combines the various components of the treatment process into a single unit. Since package plants use standard designs and factory-built treatment units that are sized, assembled, and delivered directly to the customer instead of being built on site, they have the potential to significantly reduce engineering and construction costs associated with a new water treatment system.

$20/HH/YR for other systems serving fewer than 10,000 people. This assumes 80 percent removal on average, and does not include the possibility of an AMCL. For systems serving fewer than 10,000 people and adding disinfection treatment (assuming 50 percent would add such treatment), costs would increase approximately $10 to $100/HH/YR (USEPA, 1994). These cost estimates are in the process of being updated.

Granular Activated Carbon. GAC is another potential compliance technology for small drinking water systems. GAC treatment involves passing the influent water through a column of GAC filter media. As the water passes through the media, the radon gas tends to accumulate and decay at the surface of the carbon material. Under the proper conditions, GAC rivals aeration in its radon removal efficiency. GAC also may be an attractive alternative when systems do not want to deal with radon emissions from aeration. However, except for very small water systems, GAC is unlikely to be cost-effective.[4] EPA is exploring whether or not GAC used in a point-of-entry (POE) mode may be cost-effective for the smallest water systems. GAC POE units treat the water at a point just before it enters the household, which for a small enough number of households can be cheaper than treating all the water at a central treatment plant. However, since aeration treatment is generally very affordable, GAC POE treatment would probably be less expensive only under special circumstances, e.g., for very small systems where air permitting and off-gas treatment may be required.

In general, GAC POE devices can be cost competitive with aeration treatment technologies for the smallest system sizes, depending on site-specific factors. However, since aeration treatment avoids many of the problems associated with GAC and is usually affordable, GAC treatment may be competitive for only a small number of systems.

3.2 Monitoring

Monitoring for radon in drinking water will be required under the regulation for systems relying wholly or partially on ground water as sources of drinking water. Systems relying exclusively on surface water will not be required to monitor for radon. EPA is currently assessing potential monitoring options. In 1991, EPA proposed liquid scintillation and de-emanation as analytical methods for radon in drinking water. The choice was based on the following factors:

- Reliability of the methods to detect and measure radon in water over a range of concentrations, including the 1991 proposed MCL of 300 pCi/L;

- Specificity of the methods to detect radon in water;

- Availability of equipment and trained personnel;

[4] The costs of GAC were not estimated for the 1991 proposal because GAC was not proposed as the best available technology. EPA is presently developing these cost estimates in support of the new proposal.

- Potential of the methods to quickly measure radon in water consistent with anticipated data quality objectives;

- Potential of the methods for routine use, consistent with the anticipated sample load; and
- Cost of analysis. EPA estimates that prices currently range from approximately $40 to $75 per sample, but can be lower if more tests are performed at one time. This brackets the 1991 estimate of unit sample costs (i.e., $50/sample). There is no clear correlation between the estimated price and the method cited by laboratories.[5]

At present, the most likely candidates for the proposed analytical methods are the same methods proposed in 1991. Since 1991, the liquid scintillation counting (LSC) method has been published as "standard method 7500-Rn"; this method is very reliable down to 100 pCi/L. The proposed holding time (i.e., between collection and analysis of the sample) found in the published method is four days, as was the proposed holding time in 1991. This holding time will likely be proposed again. To collect the water sample, system staff may be required to follow a specific sampling protocol, such as the immersion technique, which involves immersing the tube upside down in water and capping it under water, ensuring there are no air bubbles in the tube.

Initially, more frequent monitoring, possibly four times during the first year, may be required. Sampling frequency may be reduced to once a year if the average of the four consecutive samples is less than the MCL. If analysis of occurrence data indicates that radon levels may vary significantly over short periods of time (e.g., one year), then more frequent monitoring may be required initially during the first year or quarterly monitoring may be continued for more than a year. Initial samples may be required from every entry point to the distribution system which is representative of each well after treatment and storage. In special cases, initial samples may also be taken from the distribution system. The purpose of distribution system samples would be to determine whether sources of radon are deposited in the distribution system, as has been reported in one community. After the initial round of sampling, sample collection from the distribution system may no longer be required if the radon levels in the distribution system sample are lower than the radon levels in the sample collected from the entry point. Monitoring frequency may be reduced to once per three years if the State determines that the system is reliably and consistently below the MCL.

3.3 Multi-media Mitigation Program Guidelines

Under the 1996 SDWA Amendments, if EPA proposes an MCL "more stringent than necessary to reduce the contribution to radon in indoor air from drinking water to a concentration that is

[5] EPA contacted six laboratories that performed radon analysis and asked for approximate per sample price. The two laboratories that cited de-emanation provided prices of $45 and $75. The laboratories that used a liquid scintillation counting method provided estimates from $40 to $70.

equivalent to the national average concentration of radon in outdoor air," EPA must establish an "alternative MCL." The AMCL is to be set at a level which would "result in contribution of radon in drinking water to radon levels in indoor air equivalent to the national average concentration of radon in outdoor air."

The level of the AMCL is linked to the water to air transfer factor and the national average outdoor radon level. If the transfer factor from water to air is 10,000 to 1 and the national average outdoor radon concentration is between 0.2 pCi/L to 0.4 pCi/L in air, then the midpoint estimate of 0.3 pCi/L in air would be equivalent to 3,000 pCi/L in water. The NAS will provide information on key factors (the water to air transfer factor and the national average outdoor radon level) that EPA will use in setting the AMCL.

The provision for an AMCL may provide flexibility to States and water supply systems in reducing radon-related risk, recognizing that the greater risk in a home is often from radon in soil gas. If an AMCL is established, EPA must publish guidelines for multi-media radon mitigation programs, after notice and opportunity for public comment and in consultation with States. EPA's Office of Radiation and Indoor Air (ORIA) is developing these guidelines. The guidelines will be published for public comment with the proposed rule for radon in drinking water in August, 1999.

Using the guidelines, States may develop and submit to EPA for approval a multi-media mitigation (MMM) program to reduce radon levels in indoor air. The SDWA allows the program elements to include "public education, testing, training, technical assistance, remediation grant and loan or incentive programs, or other regulatory or nonregulatory measures" [§1412 (b)(13)(G)]. These elements are similar to some of the activities currently being done in existing radon programs in 48 States. The NAS report may also provide some information on the risk reduction benefits of various approaches to reducing radon in indoor air, which EPA will consider in developing the MMM program guidelines. A State's MMM program will be approved if it is expected to achieve health risk reduction benefits equal to or greater than what would be achieved through compliance with the MCL. In other words, an approved MMM program will need to "make up the difference" in exposure (i.e., risk reduction) between the MCL and the AMCL by reducing exposure (risk) from radon in indoor air. If EPA approves a State MMM program, public water supply systems in the State may comply with the AMCL. If a State does not have an approved program, any public water system may submit a program for approval by EPA according to the same criteria, conditions, and approval process that would apply to a State program. EPA will evaluate previously approved programs every five years.

4. APPLICABLE SMALL ENTITY DEFINITION

EPA's authority under SDWA extends to all "public water systems." The law applies the term "public water system" to water utilities and a wide range of businesses (e.g., campgrounds, factories, and schools). As part of the 1996 SDWA Amendments, Congress expressly addressed the issue of small system size and provides that the EPA Administrator may allow regulatory relief for systems serving 10,000 or fewer people. The Office of Ground Water and Drinking Water (OGWDW), therefore, defines a small system as one that serves 10,000 or fewer people. However, the Small Business Administration (SBA) regulations typically define a small business in terms of either total revenues or total employees. Under SBA's definition, a "small," privately owned water utility would be one with revenues of less than $5 million. Data from the Community Water System Survey (CWSS) indicate that the median revenue of a community water system serving between 3,300 and 10,000 people is $605,000. OGWDW thus believes that systems serving less than 10,000 people have annual revenues well below $5 million. The SBA definition also would not distinguish public water systems that have stronger technical expertise and revenue sources from those that do not. To focus OGWDW's resources on the need and concerns of the systems that really need the assistance, and to be consistent with the 1996 SDWA Amendments, OGWDW defines a small business as any business that owns a public water system that serves 10,000 or fewer people.

5. SMALL ENTITIES THAT MAY BE SUBJECT TO THE RULE

For the purposes of regulating contaminants in drinking water, EPA divides public water systems into two main types: community water systems (CWSs) and non-community water systems. Non-community water systems are further divided into non-transient non-community water systems (NTNCWSs) and transient non-community water systems (TNCWS). The radon in drinking water rule being considered would apply only to CWSs and NTNCWSs.

The radon rule will likely affect CWSs and NTNCWSs that draw at least some of their supply from ground water. Systems which draw their supply from surface water only would not be affected by the rule, nor would systems considered to be TNCWS (i.e., systems catering to transitory customers in non-residential areas such as campgrounds, motels, and gas stations). Surface water systems will not be affected because most radon in surface water is released into the air before the water reaches its destination. Radon in surface water is expected to be at very low levels. In the case of TNCWSs, the duration of exposure is considered to be occasional and infrequent and would pose minimal health risk to the public.

Community Water Systems (CWSs) *serve at least 15 service connections used by year-round residents or regularly serving at least 25 year-round residents. Examples include homes, apartments, and condominiums occupied year-round as primary residences.*

Non-Transient Non-Community Water Systems (NTNCWSs) *regularly serve at least 25 of the same persons more than six months per year. Those regularly served by NTNCWSs are served at least four days per week for at least 26 weeks per year. Examples include schools and office buildings.*

As shown in Exhibit 1, CWSs and NTNCWSs potentially affected by the radon rule can be divided into five size categories, ranging from systems serving as few as 25 to 100 persons to systems serving as many as 10,001 to >1 million persons.

For the purposes of this SBREFA analysis, all the systems that serve fewer than 10,000 people qualify as "small entities." EPA estimates that there are 40,525 ground water CWSs and 19,218 ground water NTNCWSs that serve fewer than 10,000 people (USEPA, 1998). These estimates are continuing to undergo refinement.

Exhibit 1
Total Number of Community Water Systems and Non-Transient Non-Community Water Systems
(Only Ground Water Systems That Do Not Purchase Water)

Persons Served	Number of Community Water Systems [a/]	Average Radon Concentration in Community Water Systems (pCi/L) [b/]	Number of Non-Transient Non-Community Water Systems [a/]
25 to 100	14,094	844	9,681
101 to 500	14,294	684	6,891
501 to 3,300	9,745	284	2,592
3,301 to 10,000	2,392	204	54
10,001 to >1M	1,448	205	7

Note: EPA is defining "small systems" as those that serve fewer than 10,000 people. This cut-off point is represented by a heavy line in the table.
These are preliminary estimates of the numbers of community water systems and non-transient non-community water systems and are subject to revision pending further review of the Safe Drinking Water Information System (EPA's national regulatory database for the Drinking Water Program). The estimates are continuing to undergo refinement.
[a/] USEPA, 1998.
[b/] USEPA, 1994.

6. SUMMARY OF SMALL ENTITY OUTREACH

To facilitate regulation development, EPA has actively involved interested parties in the development of the proposed rule. As part of these efforts, EPA has provided several opportunities for input following the 1996 SDWA Amendments, in addition to the opportunity for public comment on the 1991 proposed rule. Three public meetings—in Washington, D.C., San Francisco, and Boston—were held in 1997. The initial small entity conference call was held on May 11, 1998.

6.1 Public Comment on 1991 Proposed Rule

EPA requested comments on all aspects of the 1991 Notice of Proposed Rulemaking (NPRM). In total, there were more than 600 comments on the 1991 NPRM. Of the comments received, 289 were from public water suppliers, 89 were from individuals, 76 were from local governments, 52 were from States, 48 were from private companies, 43 were from trade/professional organizations, 12 were from Federal agencies, 10 were from health/environmental organizations, 3 were from members of Congress, and 2 were from universities. EPA received additional comments at public hearings on September 6, 1991, in Washington, D.C. and on September 12, 1991, in Chicago, Illinois.

6.2 Stakeholder Meetings

EPA conducted one-day public meetings in Washington, D.C. on June 26, 1997, in San Francisco, California on September 2, 1997, and in Boston, Massachusetts on October 30, 1997, to discuss its plans for developing a proposed NPDWR for radon-222. EPA presented information on issues related to developing the proposed NPDWR and solicited stakeholder comments at each meeting.

6.3 Small Entity Representative Conference Calls

On April 24 and 29, 1998, EPA/Office of Ground Water and Drinking Water distributed background information and materials to SERs to review (See Appendix A for list of documents). On May 11, 1998, EPA held a SER conference call from Washington D.C. to provide a forum for SER input on key issues related to the planned proposal of the radon in drinking water rule. These issues included, but were not limited to: (1) issues related to the rule development, such as radon health risks, occurrence of radon in drinking water, treatment technologies, analytical methods, and monitoring; and (2) issues related to the development and implementation of the multi-media mitigation program guidelines.

Thirty people participated in the conference call. The participants included 13 SERs from small water systems from Arizona, California, Nebraska, New Hampshire, Utah, Washington, Alabama, Michigan, Wyoming, and New Jersey.

Appendix A to this report provides a summary of the discussion during this call along with a list of all invitees and participants.

On August 4, 1998, The Small Business Advocacy Review (SBAR) Panel for the radon in drinking water rule distributed additional information to the SERs for their review. The materials included a table of EPA's 1993 analysis of radon MCL alternatives and additional information about radon in indoor air and development of the MMM program. The SERs were asked to review the new materials and to provide any additional comments to the Panel at an August 10, 1998 conference call meeting with the Panel and in writing after the meeting. The SERs were asked to comment on four main areas, which are small systems variances, availability of affordable technologies, communication with water customers, and the MMM program. A summary of the meeting and list of documents distributed to the SERs is included as Appendix B.

7. SMALL ENTITY REPRESENTATIVES

EPA, in consultation with the SBA and OMB, invited the following 23 SERs to participate in its SBREFA consultation process. Many of these representatives have also submitted written comments. A record of these comments is provided in Section 8 below.

Mr. James Baily, Superintendent
Warner Village Water District
Warner, NH

Mr. Bob Beaver, Principal
Adams Friendships Schools
Adams, WI

Mr. Greg Bouc, Utility Superintendent
Village of Valpariso, NE

Mr. Ken Bruzelius
Midwest Assistance Program, Inc.
New Prague, MN

Mr. Bob Campbell
Wilson School, Teton County School District
Jackson Hole, WY

Mr. Doug Evans, Mayor
Salt Lake County Service #3
Snowbird, UT

Mr. Paul Gardner
Queen Creek Water Co.
Queen Creek, AZ

Ms. Shirley Glynn, Clerk
Bates Township
Iron River, MI

Mr. Lynton Godwin
City of Plains
Plains, GA

Mr. JD Hightower, City Planner
City of Escalon
Escalon, CA

Mr. Jon Hirst
Southeastern Rural Community Assistance
Project, Roanoke, VA

Ms. Kaye Kiker
Sumter County Water Authority
York, AL

Mr. Michael Knox, Superintendent
Cherry Valley and Rochdale Water District
Rochdale, MA

Mr. David Monie
GPM Associates, Inc.
Cherry Hill, NJ

Paul Noran
Consumer Water Company
Portland, ME

Mr. Ronald Payne
Payne Utilities, Inc.
Conroe, TX

Mr. Al Ricksecker, Secretary Treasurer
Brooklyn Tapline Co., Inc.
Monroe, UT

Jesse L. Royal, Vice President
Sydnor Hydrodynamics, Inc.
Richmond, VA

Mr. Jim Sheldon
Cedar Knox Rural Water Project
Hardington, NE

Rafael A. Terrero
Florida Water Services Corporation
Apopka, FL

Mr. Dale Tyler
New Utsalady Water System
Camano Island, WA

Mr. Gary Walter
Tuolumne Utilities District
Tuolumne, CA

Ms. Nancy Woodruff
Clarkston United Methodist Church
Clarkston, MI

8. SUMMARY OF WRITTEN COMMENTS FROM SERs

OGWDW received 15 sets of written comments from SERs following the May 11, 1998 and August 10, 1998 conference calls. Exhibit 2 provides a record of the comments, and is followed by a summary of the main issues raised by the SERs in their written submittals. The complete written comments are provided in Appendix C.

Exhibit 2
List of SER Written Comments

Name	Organization	Date Received	Number of Pages
Lynton Godwin	City of Plains, GA	5/20/98	2
Nancy Woodruff	Clarkston United Methodist Church	5/22/98	2
Jim Bailey	Warner Village Water District	5/25/98	2

Name	Organization	Date Receive d	Number of Pages
Dale Tyler	New Utsalady Water District	5/26/98	½
Doug Evans	Salt Lake County Service Area #3	5/27/98	3
Al Ricksecker	Brooklyn Tapline Company, Inc.	5/27/98	3
Jim Sheldon	Cedar Knox Rural Water Project	5/27/98	2
David Monie	G.P.M. Associates, Inc.	5/28/98	½
Gary Walter	Tuolumne Utilities District	5/29/98	5
Paul Noran	Consumers Water Company	6/12/98	2
Michael F. Knox	Cherry Valley and Rochdale Water District	6/18/98	2
Shirley A. Glynn	Bates Township, Iron County	6/25/98	1
Greg Bouc	Village of Valparaiso	6/29/98	1
J.D. Hightower	City of Escalon	8/17/98	2
Dale Tyler	New Utsalady Water System	8/17/98	2

8.1 Number of Small Entities

The SERs did not provide any comments specifically addressing estimates of the small entities that would be affected by the rule. One SER, however, suggested that EPA should standardize its categorization of public water system size by number served to alleviate SER confusion when considering multiple regulatory reports.

8.2 Reporting, Record Keeping, and Other Compliance Requirements

Sampling and Monitoring

About half the SERs provided written comments addressing the issue of sampling and monitoring. The concerns were associated with the costs of transportation of samples to labs, the reliability of detection methods, availability of certified labs to perform required testing, staff training, and substantial laboratory testing fees. One SER was concerned about the 4-day holding time requirement for radon testing. This SER also commented that there would be an administrative burden associated with the high degree of long distance coordination with the lab and that the cost of $60 per radon test was too high. However, another SER believed that the costs would decrease as the demand for sample testing as the demand for sampling and testing increased in the coming years.

One SER expressed the concern that small systems may not be able to justify or absorb the cost of radon testing compared to larger systems. Two SERs were concerned with the need for staff training on sampling of radon, however another SER indicated that a water treatment plant operator is highly trained and would be knowledgeable about proper sampling techniques. The SER also stated that the proper sampling method for radon is the same for volatile organic compounds. As a result, the SER does not see the need for a new or different sampling method just for radon.

Another SER commented that the logistics of the sampling/monitoring process should be made clear to the systems beforehand to allow smaller systems, with fewer resources, to comply more easily. The SER further suggested that it would be easier for a smaller system to comply if the radon testing was part of a local water testing requirement, such as an annual county testing cycle. If this was not possible, the SER thought the testing cycle should have a "generous" timescale, as in the Copper and Lead Rule, of perhaps once every 10 years after a finding of initial compliance. One SER commented that the laboratory performing the testing should also collect the field samples and that sampling should only be necessary at the entry points. Another SER stated that testing requirements, if imposed, should only be for water from the ground water supply well up to the water mains. In addition, the SER further suggested that a reasonable period of time for testing would be once every 3 to 5 years.

Treatment

A number of SERs thought the long-term consequences of treatment were not being adequately considered in the rule development. For example, there is a potential for creating a greater problem of waste in the form of radioactively contaminated coal beds from GAC filtration. One SER even believed this might lead to the abandonment of well sites in areas where waste handling issues were a major concern.

Some SERs stated that many PWSs typically use multiple ground water sources that could serve to reduce the cost impact on the system by negating the need for aeration (reducing costs associated with off-gassing and downstream disinfection) or GAC filtering at the point of entry (reducing costs associated with waste disposal). Another SER suggested that EPA should make provisions to allow systems to actively blend their ground water with surface water supplies.

Compliance Costs

Cost was the most significant concern of almost all the SERs, cross-cutting most other commenter issues. All but one of the SERs commented on the potentially high costs that could result from compliance with the radon regulation. The SER comments regarding cost generally focused on three main issues:

- *Capital Costs for Treatment.* One SER commented that for systems serving fewer than 500 people, the costs associated with installing aeration will be $100 to $250 per household per year. He stated that the incremental cost for radon reduction will push the cost of water above the level of affordability for many small systems. Another SER commented that in order to use aeration in his system, it would be necessary to first bring the ground water up to the air (which increases energy costs), construct a second pumping system after aeration because the iron/manganese filters currently used in his system are pressure filters, and finally take into account and correct for corrosivity in the water, increasing the cost of the finished water product. Some of the SERs raised such concerns as the need for additional land costs to set up the aeration equipment, increased treatment costs for water with radon and other constituents unique to each system (e.g., iron, manganese), and the necessity of pre- and post-treatment of the aerated water. One SER, for example, stated that many of its well installations for small systems are land-locked and would require a superstructure above the existing treatment facility to accommodate an additional treatment process. Another SER said that compared to other treatment options, aeration requires a "relatively low initial investment" (in the range of $40,000 to $50,000), and the use of a package or off-the-shelf aeration treatment plant has the potential to further reduce engineering and onsite construction costs.

- *Operation and Maintenance Costs.* The SERs generally believed the costs of operation and maintenance are likely to be high. These costs would involve personnel to maintain equipment (which many small systems lack), long-term maintenance of the equipment (such as cleaning, acid washing, and repairs), labor involved in preventive maintenance, long-term post-treatment of water, and waste handling costs needed to properly deal with spent carbon beds contaminated with radioactivity. One SER commented that the operation and maintenance costs of aeration treatment are likely to be "reasonable," on the order of $2,500 to $3,500 per year. In contrast, the SER said it would be too costly and time consuming to operate and maintain GAC as a POE device when there are a significant number of devices.

- *Administrative Costs.* A number of SER comments dealt with issues involving administrative costs arising from State regulatory compliance, the cost of public hearings addressing the regulation, permitting fees and regulatory reimbursement costs, and the costs associated with the need to train or hire additional staff and certified personnel. One SER suggested that EPA should consider local or State requirements for hazardous waste management, public acceptance, and air scrubbing requirements, which would likely increase administrative costs as well. Another SER expressed concern about the liability exposure associated with the disposal of spent material. This same SER said that the use of GAC POE units would create the unique problem of having to educate "the homeowner as to why it is being installed in my house and will it harm my family?"

8.3 Relevance of Other Federal Rules

Three SERs submitted comments regarding the possible relevance of other Federal rules. One SER noted that the radon rule may conflict in some ways with the Lead and Copper Rule and the Ground Water Rule regarding corrosion and vulnerability of ground water to contamination from open aeration systems. The SER believed that aeration could cause a ground water system to become non-compliant under disinfection regulations even if that system was not previously vulnerable. Another SER expressed the concern that disinfection would still be required after treatment and that disinfection would create other water quality problems, such as precipitation of iron and manganese.

Another SER stated that measures required to comply with the radon rule at various well sites could affect or compromise compliance with other rules, including the Lead and Copper Rule. By causing changes in the pH level and corrosivity of the water, various well sites would require further improvements, adjustments, and expense.

8.4 Suggested Regulatory Alternatives

AMCL and MMM Program

Overall, there was consensus among the SERs that the implementation of the MMM program needs to be clarified, particularly with regard to the exact role of a small system in such a program. One SER's main concern with an MMM program was the possibility of passing along hidden costs to the customer due to a State's oversight infrastructure, the funding for which is ultimately provided by the consumer. Another SER believed that small systems have neither the authority nor the financial capability to carry out their own MMM program, and therefore stated that MMM programs cannot realistically be developed by small systems. Instead, they must rely on larger entities, such as the State, to meet the criteria for allowing the AMCL to be utilized. In a related comment, one SER stated that rural water systems, along with private systems, would be denied use of any AMCL since they lack the authority over indoor air. One SER stated that since small systems incur the greatest cost impact in meeting a more stringent MCL, they should have an easier avenue open to them for using the AMCL, rather than the MCL. Another SER further expressed concern that States having pre-existing indoor radon programs would be penalized by the use of a benchmark based on current levels of radon reduction. He commented that States or other entities should be rewarded rather than punished for having had a strong radon risk reduction program in the past.

Some of the SERs said their participation in an MMM program would be conditional on the details of an actual program. One SER stated that if the State developed an approved MMM program, and if the system's water exceeded the MCL ultimately set by EPA, then the PWS would seriously consider participation in such a program. However, the PWS would only consider participation in the program if it would bring the PWS down below EPA's AMCL, and if the system could comply with the State's MMM. Another SER stated that she would consider participating in an MMM program if the State developed one, but was concerned about any legal consequences of not meeting a known safety standard.

One SER asked whether EPA currently had any models or examples of MMM programs for the small systems to consider. The SER did not believe that EPA made clear the actual implementation of such a program (e.g., how the PWS might deal with public questions and concerns). Another SER requested that EPA simplify the MMM program guidelines for PWSs by addressing the radon hazard in drinking water with PWSs, and addressing indoor air radon concerns with heating, ventilation, and air-conditioning (HVAC) specialists. Another SER suggested that a MMM program element could be including radon detectors and radon resistant construction techniques in building codes, which would allow cities to act and enforce in a fashion that is traditionally a city function.

Finally, a SER commented that an MCL and AMCL for radon will be difficult for customers to grasp. The SER stated that the actual indoor radon level may be significantly different than the average outdoor radon level. As a result, an AMCL link based on an average outdoor radon level may pose significant risks where the indoor radon air level is much higher than the average outdoor radon level. In a related comment, the SER also stated that developing guidelines and implementing an effective MMM program will be a major challenge. This is in part due to the fact that the AMCL for a system may be many times higher than the MCL. In cases where systems have drinking water radon levels at the AMCL, it may be difficult to assure customers that their water is safe, despite the higher radon levels.

8.5 <u>Other Issues</u>

Approximately half of the SERs commented on the proposed level of the 1991 MCL of 300 pCi/L, all believing it was unrealistically or unreasonably low. Two SERs suggested that an MCL closer to 1,000 to 5,000 pCi/L would be more reasonable. In support of this suggestion, one SER pointed to the MCL of 1,000 to 2,000 pCi/L that the State of New Hampshire is proposing. While the SER also cited the 20,000 pCi/L MCL for radon in Maine, it was suggested that this was probably too high, and that New Hampshire's MCL was perhaps a better number for EPA to consider. Another SER wanted to know how EPA arrived at the 1991 300 pCi/L proposed MCL, and asked if the 10,000 to 1 number is common in comparing national air levels to drinking water levels. One SER stated that, "If the MCL for radon is set realistically for [the state], based on the ambient level of radon in air in the state, and proper weight is given to the water to air transfer in all cases, then systems in that state should not have a problem with compliance." Finally, a SER suggested it is impossible to accurately predict the impacts on small entities of EPA's proposed MCL for radon because the NAS report that will influence decision making and the health risk reduction and cost analysis are not yet completed. For this reason, the SER believed that it may have been more prudent to delay a SER meeting until those products were made available.

Many of the SERs believed the high costs of compliance are unjustified when compared to the risk reduction that would be achieved. Several SERs, for instance, commented that they did not think the prevention of 84 cancer cases per year was a justifiable number considering the relatively huge cost of implementing the new MCL. Similarly, one commenter questioned the documented science supporting a new MCL of 300 pCi/L, asserting that such an MCL would just create an unnecessary and unfunded government mandate. This same SER questioned why the department of water quality is being used to control the main concern of radon, when the problem exists in the air and not the water in people's homes. Five SERs pointed to potential rate increases for their customers of 43 to 325 percent, which they considered to be too high. One SER commented that, based on the cancer risks, there should be an MCL for radon in drinking water, but expressed concern over the significant treatment costs and affordability for small systems. Another SER closed his comments by saying everyone wants safe and clean drinking water, but he is not convinced all rate payers are ready to dig into their pockets for what they view as another "needless government rule."

Approximately a third of the SERs expressed concern that the regulation did not adequately take into account the variability among systems, or the resulting logistical problems this could cause. For example, different systems have varying water quality that needs to be considered in any treatment process. Also, different water temperatures potentially affect treatment execution, and in some systems, there is a need for extensive post-aeration disinfection. One SER commented that EPA's regional radon occurrence is regional and a "one size fits all" approach does not take into account individual systems that may not have a radon problem but would still incur the costs of compliance.

Finally, one SER suggested that the rule include a waiver process for wells that are used for supplemental or back-up purposes such as wells used less than 60 days per year. For this SER's water systems, which mostly use ground water wells for this purpose, such a waiver provision would limit health exposure and risks and help to mitigate costs. Another SER representing a church (NTNCWS) noted that very little water is ingested by any one person even though the building itself is used regularly for services, meetings, and dinners.

9. PANEL FINDINGS AND DISCUSSIONS

It is important to note that the Panel's findings and discussion are necessarily based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process and from public comment on the proposed rule.

EPA is interested in input from small entities at an early stage in the regulatory development process when their comments and insights can inform the Agency's thinking about fundamental issues of rule design and scope, and can be taken into account in a meaningful way. Early involvement allows small entity perspectives to be considered as the Agency develops the supporting analyses for the rule.

Two Panel members expressed concern that the Panel was convened too early in the rulemaking process to properly fulfill its responsibility to solicit input from SERs regarding "significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." These two Panel members were concerned about the lack of a draft proposed rule for the SERs to comment on, or suggest alternatives to, and by the fact that the assessment by the NAS of radon risk from drinking water exposure and the health risk reduction benefits associated with measures to reduce radon in indoor air had not been completed. Near the end of the Panel process, when it became clear that the NAS report (originally expected at the end of July) would be delayed by several weeks, two SERS specifically requested that the Panel extend its deadline beyond the sixty-day term prescribed by SBREFA to allow the SERs time to consider the NAS report in preparing their final comments. This request was supported by two Panel members, who believed that it would also be helpful to the Panel to consider the NAS report in preparing this report, given the significant statutory role of the NAS report in the development of the rule.

In denying the request to extend the Panel deliberative period, the Chair assured the Panel that EPA would provide the NAS report to both the SERs and the Panel members for their review and comment whenever the NAS released it, even though the Panel itself might be formally concluded by that time. In keeping with EPA's policy of appropriate outreach and accommodation throughout the rulemaking process, the Agency will seriously consider any concerns raised on behalf of small entities even after the close of the Panel review period. EPA also notes that the statutory requirements for the radon regulation provide an additional opportunity for public comment before EPA publishes the proposed rule. The Health Risk Reduction and Cost Analysis for various MCL options will be published for public comment in February 1999, and the SDWA requires EPA to include a response to all significant comments in the preamble of the proposed rule.

The Chair also noted that there are advantages and disadvantages to convening the Panel either sooner or later in the rulemaking process. The primary advantage of an earlier Panel is that the input from SERs is available to the Agency at a point when regulatory options are still being developed, and it can help shape those options by advising the Agency on desirable additional analysis while the Agency still has time to undertake that analysis. The disadvantage is that there is often less specific information available to SERs on which to base their comments. The primary advantage of a later Panel is that the rulemaking record is nearly complete and available for more comprehensive review. The disadvantage is that, since the Agency is frequently working under the pressure of an approaching deadline, it may have only limited capability to examine small-entity recommendations in sufficient detail and on the basis of an adequate factual record to support substantive modifications to a previously identified option.

In the present case, a number of SERs expressed frustration at the difficulty of providing meaningful input on the impacts of an MCL on small systems without having had a chance to review the underlying risk analysis in the NAS report. Instead, the Panel provided SERs extensive information on the 1991 proposed rule, 1993 costs and benefits analysis of various MCL levels, the new statutory provisions of the 1996 amendments, and EPA's current thinking on the implementation of those provisions (e.g., treatment, monitoring, multi-media mitigation program, AMCL).

While acknowledging that the NAS report would provide valuable additional information, and that the all participants had expected the NAS report to be released during the Panel process itself, the Chair determined that the information already available formed a sufficient basis for the Panel to "collect advice and recommendations of each individual small entity representative" on Regulatory Flexibility issues, including the statutory elements of an Initial Regulatory Flexibility Analysis. EPA further notes that the NAS report, while an important input to the rule development process, will not be directly translatable to an MCL. Rather, a host of risk management considerations will be evaluated and a full consideration of cost and benefits will be performed in order to determine a proposed MCL level. In the view of the Chair, since new information is developed continuously during the course of a rulemaking, to extend the Panel beyond its statutory term on the basis that useful information is not yet in hand might open any Panel to an indeterminate sequence of extensions, which EPA cannot accommodate within the limitations of its resources and the rulemaking schedule. Despite this the Chair acknowledges that there are strong, conflicting views on the question of when a Panel should most appropriately convene. The Chair will continue to work with all three Agencies to select the time for convening future Panels that best balances the competing goods of early consultation and fully-formed documentation.

While acknowledging the Chair's concern with the agency's resources and rulemaking schedule, the two Panel members who supported the SERs' extension request do not believe this concern should take precedence over SBREFA's stated purpose of encouraging the effective participation of small businesses in the Federal regulatory process. These Panel members believe that the additional information in the NAS report could have significantly enhanced that participation. They note that the quantitative analyses provided to small entities were at least 5 years old, and thus could not reflect significant changes in the statutory framework for promulgating a radon standard that occurred since they were performed. These changes include extensive new analytical requirements and make them an integral part of the standard setting process. The NAS report itself is one of the primary elements of these new requirements. In particular, it is expected to include updated information on the risks form exposure to radon in drinking water, both through inhalation and ingestion, the risks from exposure to radon in indoor and outdoor air, and the effectiveness of various measures to reduce these risks. The magnitude of these risks and the potential benefits from measures to reduce them are central to several of the major concerns raised by SERs and discussed by the Panel. These Panel members noted that the Panel Report will not be released to the general public for nearly a year following its completion.

Under these circumstances, they saw little practical reason why its completion could not have been delayed for a few weeks in order to allow consideration of the NAS report.

Any options the Panel identifies for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, protective of public health, and consistent with the Safe Drinking Water Act.

9.1 Number of Small Entities

No commenters questioned the information provided by EPA on the number and types of small entities which may be impacted by the radon rule. Because EPA maintains the national Safe Drinking Water Information System (SDWIS) database, with information about all public water systems in the country, and because EPA is updating its 1991 occurrence estimates with more current State data, the Panel believes that EPA will have very good information about the number and types of systems impacted by the radon in drinking water rule. The Panel is aware, however, that concerns have been raised about the number of wells that EPA uses in its cost analysis. There has been a significant decrease in the number of reported systems over the past few years. This is accounted for partially by a purging of defunct systems from state records, and partially by consolidation of existing systems. In such cases, there may or may not be a corresponding closure of wells. The Panel recommends that EPA continue to refine its estimates of the number of affected wells.

9.2 Potential Reporting, Record Keeping, and Compliance Requirements

9.2.1 Cost of Compliance and Treatment

Almost all SER commenters expressed concern over the potentially high costs of the rule. Several stated explicitly that costs ranging up to $250 per household per year, as previously estimated for an MCL of 300 pCi/L for systems in the 25-100 size category, would not be affordable for their customers. In some cases, this determination was based on a general perception that their customers would object strongly to paying such a high price for a very small reduction in cancer risk ("less than one case per year in the entire state of Utah," as one put it). However, only one SER mentioned a specific quantitative basis for this determination (that water costs should not exceed 1% to 2% of median household income for the service area).

Only one SER, representing a system serving 4,200 people, stated that the costs of aeration for his system would be reasonable. Data provided by this SER indicated that annualized costs per household would be under $10. Even so, this SER expressed skepticism that "rate payers are ready to dig into their pockets for what they view as another needless government rule." Several SERs noted their concern about a lack of current information on which to base a discussion of the impacts of the rule on small systems.

Since EPA is interested in input at an early stage in the regulatory process, EPA has not yet identified what concentration levels it will consider for the proposed MCL or what the costs and benefits of a particular MCL level might be. In fact, EPA cannot do so until it receives the National Academy of Sciences report on radon risk from water and risk reduction benefits form mitigation of radon in indoor air. Thus, any quantitative discussion by the SERs or the Panel on the possible national costs and benefits of the rule must necessarily rely on the options and analyses presented in the 1991 proposed rule, as updated in a September 1993 Draft Regulatory Impact Analysis (RIA) which formed the basis of the cost and benefit estimates in the Agency's 1994 Report to Congress.

EPA estimated in 1993 that its proposed MCL of 300 pCi/L would cost $286 million per year nationally and avert 88 cancer cases annually. This was the lowest of several cost estimates produced at about that time. In 1991, the American Water Works Association (AWWA) estimated that it would cost $2.5 billion nationally to achieve an MCL of 300 pCi/L, while the Association of California Water Agencies (ACWA) estimated that it would cost $520 to $710 million in California alone. The discrepancies among the EPA and trade association estimates are explained by differing assumptions regarding the numbers of affected systems and unit treatment costs, and the different interest rates used to annualize capital costs. EPA has taken a number of steps to better define these various assumptions including convening of a ‘blue ribbon panel” of utility experts in December 1997. The Panel also understands that EPA is working with AWWA and ACWA to resolve the discrepancies in the various cost estimates and develop a set of estimates that EPA and water system operators agree are realistic. The Panel applauds this effort.

In a 1993 report, the EPA Science Advisory Board (SAB) presented national cost estimates for a 300 pCi/L standard ranging from $387 to $479 million, depending on whether a 3% or a 10% interest rate was used to annualize capital costs. The SAB stated that EPA had "approached the development of the unit costs for the removal of radon from drinking water by the Packed Tower Aeration (PTA) method using a reasonable approach," but noted that, "Problems do arise in calculating the total unit costs, however, because of the assumptions made on the individual items that make up the total unit costs." The SAB noted several specific concerns, including whether EPA's estimates represented the costs industry would most likely incur as a result of the rule or the lowest possible cost industry could incur, whether PTA was really a more appropriate technology than Granulated Activated Carbon (GAC) for small systems, whether EPA had adequately accounted for differences between large and small systems in design practices and O&M costs, and whether the Agency had used an appropriate interest rate to annualize costs. With regard to this last point, the SAB noted that capital improvements for small systems require interest rates of 10% or higher and recommended that EPA use a rate higher than the 3% used in the original RIA for the 1991 proposal. In response to SAB’s recommendation, EPA used a 7% interest rate in computing the 1993 estimate of $286 million. EPA is fully considering all of the earlier SAB comments in its current evaluation of treatment technologies and costs.

Finally, EPA recently provided to the Panel a summary of 15 case studies of small systems that had actually installed packed tower aeration (PTA) to meet a radon level of 300 pCi/L. For 9 systems in the 25-500 size category, annual household costs ranged from $4.70 to $96.50; for 5 systems in the 501-3,300 size category, annual household costs ranged from $11.13 to $21.50; and for 1 system in the 3,301-10,000 size category, annual household costs were $6.43. Two Panel members were concerned that if these cost figures were based on voluntary action by water systems to control radon, they might not be representative of the costs to all systems of a national regulation, because of the greater likelihood of voluntary actions on the part of systems for which these actions would be least costly. While the spread in treatment costs for any contaminant can be quite large, EPA notes that the radon cost case studies provide costs that it believes are typical of published and unpublished small systems cost data for aeration treatment for volatile organic contaminants (VOCs), a group of regulated contaminants. For this reason, EPA feels that the spread of treatment costs shown by the radon case studies are reflective of the actual treatment costs that water systems will face when the radon rule is promulgated. Supporting arguments include the fact that the removal of any volatile contaminant by aeration involves the same set of problems as removal of radon (e.g., off-gas emissions issues, including permitting, iron and manganese control, disinfection, indirect construction costs, etc). And since radon is more easily removed than the vast majority of VOCs, aeration treatment designs for VOC removal would be over-designed compared to those designed for radon removal, meaning that capital costs for VOCs removal would be expected to be higher than for radon removal.

Based on all of this information, the Panel decided to use the EPA 1993 draft RIA as the basis of its consideration of potential costs and benefits associated with various MCL levels. The Panel supports EPA's on-going efforts to update these estimates and to ensure that they are as complete and accurate as possible. In developing requirements and guidance concerning the appropriate use of aeration or GAC, EPA should consider and include in its regulatory cost estimates, to the extent possible, the complete burden and benefits, which may include the following components: designing, purchasing and installing aeration or GAC equipment; system re-engineering; purchasing of land when there is insufficient space; additional pumping; training operators; providing additional operator time to monitor and maintain equipment; purchasing and installing disinfection treatment; pre-treating to reduce or control corrosion or the precipitation of iron, manganese, or calcium; holding public hearings; and complying with state air and hazardous waste regulations (e.g., air permitting for aeration treatment; hazardous waste management requirements for GAC).

The Panel understands that not all cost components will apply equally to all systems (e.g., more stringent air regulations in California) and that EPA will be developing a range of benefit and cost estimates for treatment to account for uncertainty in the extent to which various elements will be required.

The Panel also notes that the 1996 SDWA amendments included new provisions to help water systems, including small systems, obtain financing to install treatment. Specifically, a Drinking Water State Revolving Fund (SRF) was authorized at $9.6 billion, with $2 billion appropriated through FY 1998, to increase access to and reduce the cost of capital to water systems for infrastructure needed to reduce the most serious risks to health, provide for compliance, and assist systems most in economic need.

Finally, the Panel notes concerns expressed by several of the SERs regarding the costs and consequences of granular activated carbon (GAC) filtration treatment for radon in drinking water, including the handling and disposal of radioactive waste from spent carbon beds. The Panel understands that GAC treatment may be a cost effective treatment technology for a relatively small number of systems that meet certain site-specific conditions. However, to assist small systems in making their treatment technology decisions, the Panel recommends that EPA provide clear guidance for when GAC treatment may be appropriate as a central or point-of-entry unit treatment technology.

9.2.2 Small System Variance Technology

The Panel discussed new provisions that exist in the 1996 SDWA amendments for States to grant variances to small water systems (i.e., systems having fewer than 10,000 customers) from complying with an MCL if EPA determines that there are no affordable compliance technologies for that system's size/water quality category. The system must then install an EPA listed variance treatment technology that makes progress toward the MCL, if not necessarily reaching it. For such variances to be allowed, three "hurdles" must be passed: 1) EPA must make a determination on a national level that there are no affordable compliance technologies available for the given small system size category; 2) If there is not an affordable compliance technology, then EPA has to identify a variance technology that will aid small systems in making progress toward the MCL, without necessarily reaching the MCL—this technology must be listed as a small systems variance technology by EPA; and 3) EPA must make a finding, on a national level, that the use of the variance technology would be protective of public health. Primacy States must then also make a site-specific determination for each system to ascertain if the system cannot afford to meet the MCL, and if the use of a variance technology would be protective of public health.

EPA's preliminary assessment suggests that aeration technology will be adequate to achieve compliance with the MCL and will be affordable for all size categories of systems. In 1993, EPA estimated that at an MCL of 300 pCi/L would cost $99 per household per year for systems in the 101 to 500 size category, and $249 per household per year for systems in the 25 to 100 size category. EPA is re-evaluating the treatment costs, and case studies (discussed above) suggest that $250 may be on the high end of costs for the smallest size systems. EPA recently published a Federal Register notice in which it solicited comment on national affordability criteria under which compliance would be considered affordable if the ratio of median annual household water expenditures (nationally, for total drinking water system expenditures) to median household income (nationally) does not exceed 2.5%. Based on the 1995 Community Water System Survey, EPA estimates current median annual household water expenditures for small systems to be about $200-250, and median household income to be about $30,000. Since 2.5% of $30,000 is $750, this leaves an average of about $500/year for additional water costs (including both compliance costs and needed infrastructure improvements) that EPA believes could be absorbed by households served by small systems before a compliance technology would be considered unaffordable and a variance technology could be listed. While the costs of the radon rule for small systems will likely fall well below this household expenditure margin, the issue of affordability will play an increasingly significant role in future regulations as the margin narrows.

Two Panel members were concerned that this approach for determining national affordability does not account for the variability of treatment costs across systems, the variability of current water bills, and the variability of incomes among communities served by small systems. In particular they were concerned that an approach based on national medians would not allow states to use small system variances to address situations where the impact of installing new treatment on an individual community was severe, because the community already had especially high water costs or was composed primarily of low-income households. EPA believes that there is another mechanism in the SDWA to address cost impacts on small systems composed primarily of low-income households. These systems could be classified as disadvantaged communities under Section 1452(d) of the SDWA. They can then receive additional subsidization under the Drinking Water State Revolving Loan Fund (DWSRF) program, including forgiveness of principal. The other Panel members noted that there will be many communities competing for the limited funding available under the DWSRF and remained concerned that this funding may not be adequate to address the needs of all individual small systems that cannot afford to comply with drinking water standards

EPA further notes that high water costs are often associated with systems that have already installed treatment to comply with a NPDWR, which may facilitate compliance with future standards as well. EPA's approach to establishing the national-level affordability criteria did not incorporate a baseline for in-place treatment technology. Assuming that systems with high baseline water costs would always need to install a new treatment technology to comply with a NPDWR may thus significantly overestimate the actual costs for these systems. This was an important consideration in developing EPA's approach to determining whether compliance technologies are nationally affordable. The other Panel members agreed that compliance costs for individual systems may be overestimated for this reason in some cases. This is why SDWA provides for case specific affordability determinations by States as part of the process for granting small system variances. They do not believe, however, that national affordability criteria should be so stringent that States are precluded from making these case specific determinations until national water costs become so high that significant distress is experienced by a large number of systems.

The two Panel members further noted that the 2.5% threshold was at the high end of the range used in various earlier affordability criteria, including some issued by EPA, and higher than those used in the four sets of state affordability criteria summarized by EPA in Appendix F of "Information for States on Developing Affordability Criteria for Drinking Water." However, these State affordability criteria are intended for use in prioritizing systems for assistance from the DWSRF and are not necessarily the same criteria that the State would use to make small system variance determinations, although they are the only indication currently available to the Panel of what affordability criteria for variance determinations might look like. The Panel agreed that in assessing the appropriateness of EPA's national affordability criteria, it would be helpful to have additional information on the affordability criteria currently being developed by states to implement the small system variance provisions of the SDWA.

The Panel agreed that the issue of appropriate national affordability criteria for listing small system variance technologies should be further addressed in a venue outside of the radon SBAR Panel process because it is relevant to all drinking water regulations and not only radon.

Even if the Agency were to agree that aeration or GAC was unaffordable for enough small systems to warrant listing a small system variance technology, it would still have to identify such a technology, and this technology would have to meet the statutory criterion that it be protective of public health. Currently, the Agency is not aware of any lower cost technologies for radon compliance that could be designated as variance technologies. Furthermore, there would also be costs associated with installing a variance technology, including administrative costs, that would partially offset any savings from not installing a compliance technology. Diffused aeration, which EPA expects to list as a compliance technology for radon, can be characterized as requiring basic operator skill with low monitoring requirements, low capital cost and low relative operating cost (NRC, 1997). Thus, EPA believes that diffused aeration represents the most basic option available to systems to reduce radon concentrations.

9.2.3 Monitoring

The Panel notes the SERs' concerns regarding the impacts monitoring of radon would have upon small systems, in particular the laboratory analytical costs (which range from $40 to $75) and additional staff training for sample collection. The Panel recommends that EPA should fully consider the availability and capacity of certified laboratories for radon analysis and consider the costs of monitoring, including staff training, shipping of sample to the laboratory, and analysis. These costs should be included in EPA's regulatory cost estimates. EPA, after consultation with stakeholders and the Association of State and Territorial Public Health Laboratory Directors, believes that there will be sufficient certified laboratory capacity for radon analysis, but will further explore this issue. The Panel notes that the sampling method for radon is similar to the sampling method for volatile organic contaminants (VOCs) and recommends that EPA consider applying the VOCs sampling method to radon to reduce the need for additional training.

Furthermore, the Panel notes that a number of SERs are concerned about the frequency of monitoring after initial determination of compliance. The Panel recommends that EPA should reduce the frequency of monitoring after initial determination of compliance and consider providing waivers from monitoring requirements when a system in not at risk of exceeding the MCL. The Panel notes that EPA is currently developing a proposed approach for regulated contaminants under a separate effort which may reduce monitoring burdens for systems and increase monitoring flexibility for the States. The Panel recommends that EPA consider any burden-reduction measures proposed under this approach while developing the radon monitoring requirements. In addition, EPA should develop requirements that are simple and easy to interpret, to facilitate compliance by small systems.

9.3 Relevance of Other Federal Rules

The Panel notes the concerns of a few SERs that aeration treatment to remove radon could lead to increases in corrosivity and other contaminants of concern (e.g. lead and copper), depending on the specific characteristics of the source water and distribution system. The Panel understands that in some cases, aeration may reduce carbon dioxide levels in the water, which tends to decrease corrosivity. In other cases, aeration may increase dissolved oxygen levels, which may increase corrosivity. Therefore, installing aeration could either aid or hinder compliance with the lead and copper rule and other rules where corrosion is an issue.

The Panel also notes the concern that open-air aeration may increase the vulnerability of ground water to contamination, therefore requiring disinfection. This could result in increased microbial risk to consumers if disinfection systems breakdown or are improperly operated. It could also lead to increased risk from disinfection by products, although the majority of groundwater systems have low TOC content in their source water, making DBPs less of an issue. In addition, the Panel notes that aeration treatment would benefit systems that may need to comply with the upcoming proposed Arsenic in Drinking Water Rule because aeration converts arsenic to a chemical species (arsenic V) that is easier to remove from the water (than arsenic III).

Finally, the Panel notes the concern with potential permitting requirements for radon off-gassing from aeration towers. The Panel is not aware of any such requirements currently at the Federal level, but is aware of one state that has such requirements already for other contaminants. Such requirements may become more prevalent as the public becomes aware of, and concerned about, an increasing number of PTA systems venting radon gas directly into the atmosphere, although EPA's earlier analysis, based on the 1991 proposal, indicated that off-gassing of radon from aeration towers would not represent a significant health threat.

In developing regulations or guidance related to aeration, EPA should carefully consider these effects and allow states and systems adequate flexibility to implement treatment in the most cost-effective manner. The effects should also be appropriately accounted for in the Health Risk Reduction and Costs Analysis for the radon rule. The Panel recommends that EPA fully consider the relationship of the Radon in Drinking Water Rule with other impacted rules, such as the Ground Water Rule, Lead and Copper Rule, Disinfection By-Products Rules, and Arsenic Rule, and encourage States and systems to coordinate compliance with these rules.

9.4 Regulatory Alternatives

9.4.1 Interpretation of Safe Drinking Water Act at Section 1412(b)(13)(E)

Section 1412(b)(13)(E) of the SDWA requires the Administrator to publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for radon pursuant to this section based on the risk assessment prepared pursuant to subparagraph (B) [i.e., the NAS report] and the health risk reduction and cost analysis published pursuant to subparagraph (C). It further provides that, "In considering the risk assessment and the health risk reduction and cost analysis in connection with the promulgation of such a standard, the Administrator shall take into account the costs and benefits of control programs for radon from other sources."

The Panel spent considerable time discussing the meaning of this subparagraph and its implications for the standard setting process. The Panel agreed that it does not fundamentally alter the standard setting process established in Section 1412. Rather, the first sentence acknowledges a link between the specific radon requirements in 1412(b)(13) and the general requirements of Section 1412 for setting an MCL. In particular, under the 1996 amendments, the general standard setting process includes the following new provisions, which also apply to radon. Under 1412(b)(3)(C), the Administrator is to prepare a health risk reduction and cost analysis. Under 1412(b)(4)(C), the Administrator is to publish a determination, based on the analysis conducted under paragraph (3)(C), as to whether the benefits of a proposed MCL justify its costs. Under 1412(b)(6), the Administrator may use a determination that the benefits of a proposed MCL do not justify the costs to set an MCL less stringent than the feasible level that maximizes health risk reduction benefits at a cost that is justified by the benefits. It should also be noted that, under EO 12866, agencies are directed, to the extent permitted by law and where applicable, to assess both the costs and the benefits of an intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

Regarding the second sentence in 1412(b)(13)(E), which directs the Administrator to take into account the costs and benefits of control programs for radon from other sources in considering the risk assessment and HRRCA in connection with the promulgation of the standard, the Panel agreed that the Administrator has considerable flexibility in determining exactly how to take these costs and benefits into account. The EPA Panel members believe that the most reasonable interpretation of subparagraph 1412(b)(13)(E) is that it allows consideration of the costs and benefits of control programs for radon from other sources; but does not mean that such other costs and benefits are determinative of the MCL. EPA Panel members further noted that section 1412 was carefully constructed and reflected prior legislative efforts. Congress had set out, in considerable detail, the structure for conducting a cost-benefit analysis for various MCLs; for making a determination as to whether the benefits of a proposed MCL do or do not justify the costs; and if the benefits do not justify the costs, providing discretionary authority to set the MCL at a level other than the feasible level. In the view of the EPA Panel members, had Congress intended to alter this approach as to radon, they would have done so with clarity.

The other Panel members agree with EPA's description of the general standard setting process. They believe, however, that the second sentence in 1412(b)(13)(E) does clearly express Congress' intent that for this rule the costs and benefits be taken into account in those aspects of the standard setting process that require consideration of the risk assessment and the health risk reduction and cost analysis. They believe that the sentence quite explicitly directs the Administrator to take such costs and benefits into account ("the Administrator shall take into account the costs and benefits of control programs for radon from other sources") and quite explicitly identifies in what context they are to be taken into account ("in considering the risk assessment and the health risk reduction and cost analysis in connection with the promulgation of the standard"). They note that the process provided in the statute for the promulgation of a standard includes two provisions that are explicitly required to be based on the health risk reduction and cost analysis, the determination in 1412(b)(4)(C) as to whether or not the benefits of the proposed MCL justify the costs, and the exercise in 1412(b)(6) of the discretionary authority to set an MCL above the feasible level in the event they do not. The non-EPA Panel members believe that Congress could not have been any clearer in expressing its intent that the costs and benefits of controlling radon from other sources are to be taken into account in the implementation of these two provisions. They agree with the EPA Panel members that the Administrator has flexibility in determining how these costs and benefits are to be taken into account.

9.4.2 Setting the MCL

Perhaps the most effective alternatives for minimizing any significant economic impact of the proposed rule on small entities involve the choice of the MCL. Because EPA has not yet determined what specific concentration levels it will consider for the proposed rule, the Panel's discussion of this issue focused on the 300 pCi/L level that was proposed in 1991. Several SERs stated that they thought this level was too low, and that at least for small systems, the benefits of achieving such a low concentration do not justify the costs. One SER noted that New Hampshire has proposed a limit in the range of 1,000 to 2,000 pCi/L, while Maine has a limit of 20,000 pCi/L. This SER suggested that, "Maine's limit may be high, but New Hampshire's is certainly not low. The EPA 1991 suggested limit is extreme."

The Panel distributed information to the SERs based on the 1993 RIA showing the estimated costs, benefits, and cost-effectiveness of alternate MCLs for systems in different size categories. The Panel cautions that the data and assumptions on which these estimates are based will be revised with more up-to-date information as part of the current rulemaking process and may change significantly. Any discussion based on these estimates are necessarily tentative, but they represent the best information currently available.

For an MCL of 300 pCi/L the average cost per cancer case avoided across all system size categories was $3.3 million. Looking at small systems only, this cost rose slightly to $3.7 million. For systems in the smallest size category analyzed, however, (those serving 25-100 people), the cost per cancer case avoided was $8.5 million. These are average cost-effectiveness figures. In effect they compare an MCL of 300 pCi/L with the alternative of doing nothing. In selecting among different regulatory options, however, it is important to consider the incremental cost-effectiveness of moving from a less stringent to a more stringent option. The SDWA explicitly requires that an analysis of the incremental costs and benefits associated with each alternative MCL considered be included in the HRRCA. The incremental cost-effectiveness of moving from an MCL of 2,000 pCi/L to one of 300 pCi/L (defined as the additional cancer cases avoided divided by the additional cost) averaged across all systems is $3.8 million per cancer case avoided. For small systems only, this figure rises to $4.6 million. For systems in the smallest size category, the incremental cost-effectiveness of moving from an MCL of 2,000 pCi/L to 300 pCi/L is $13.1 million.

The cancer risk assessment on which these cost effectiveness estimates are based assumes an incremental lifetime cancer risk from radon in drinking water of 6.7×10^{-7} per pCi/L. This is composed of a 3.2×10^{-7} per pCi/L risk of lung cancer from inhalation of volatilized radon gas and its derivatives, and 3.5×10^{-7} per pCi/L risk of stomach and other cancers from ingestion of drinking water directly. The risk of lung cancer from inhalation of radon gas is well established, but the risks from direct ingestion are less well established. This is one of the issues that the NAS report will address. The Panel notes, however, that if the NAS does not agree that the evidence for cancer risk from direction ingestion is compelling and recommends that EPA consider only the inhalation risk in setting the MCL (and if inhalation risk remains the same), the costs per cancer case avoided would be roughly doubled.

Table 1 shows the average concentrations of radon found in drinking water, indoor air, and ambient outdoor air, and the number of fatal cancer cases per year that are attributable to each source. As Table 1 shows, 192 cancer fatalities are attributed annually to radon in drinking water, 520 cancer fatalities are attributed annually to the inhalation of radon in ambient outdoor air, and 13,600 cancer fatalities are attributed annually to the inhalation of radon in indoor air. Table 2 shows that for MCLs ranging between 200 pCi/L and 2,000 pCi/L the number of cancer cases avoided as a result of the standard ranges from 111 down to 21. Based on the information in these tables, two Panel members noted that a 300 pCi/L MCL would eliminate only 0.6% of the cancer fatalities attributed to radon. They were concerned that given the significant untapped opportunities to reduce the 95% of radon risk that results from exposure to radon in indoor air, it may be difficult to justify a costly drinking water standard that achieves relatively modest risk reduction.

The Panel agrees that the greater health risks posed by radon in air are well documented and that mitigation of radon in air is generally more cost effective than treatment of radon in water. The Panel further agrees that the fundamental structure of the radon provisions of SDWA, in which a radon-in-air reduction program and a potentially higher (less stringent) MCL are provided as an alternative, clearly recognizes these facts. However, the EPA panel members do not believe that the drinking water MCL can or should be established purely on the basis of comparing the cost-effectiveness of mitigating radon in air versus radon in water.

Table 1

	Annual Cancer Fatalities [a/]	Percent
Number of Annual Cancer Deaths from Radon in Indoor Air	13,600	95%
Number of Annual Cancer Deaths From Radon in Ambient Outdoor Air	520	3.6%
Number of Annual Cancer Deaths from Radon in Drinking Water	192	1.3%
Total Number of Annual Cancer Deaths Associated with Radon	14,312	100%
Annual Cancer Cases Avoided by Implementing a 300 pCi/L MCL	88 (65)[b/, c/]	0.6% (0.45%)
Annual Cancer Cases Avoided from Voluntary Air Program	100 (2,200)[d/]	0.7% (15%)

[a/] Source: USEPA, 1994.
[b/] Number in parentheses indicate lives saved at all systems fewer than 10,000 people
[c/] Source: USEPA, 1993.
[d/] Number in parentheses indicate the potential of the voluntary air program to avert cancer cases assuming 100% voluntary monitoring and mitigation.

Table 2

MCL (pCi/L)	Total Annual Number of Fatal Cancer Cases Associated with all Radon Exposures [a/]	Annual Number of Fatal Cancer Cases Avoided by Implementing MCL [b/]	Percent Reduction in Total Cancer Cases Provided by Implementing MCL
200	14,312	111	0.78%
300	14,312	88	0.61%
500	14,312	62	0.43%
1,000	14,312	37	0.26%
2,000	14,312	21	0.15%

[a/] Source: USEPA, 1994
[b/] Source: USEPA, 1993

The complete table of 1993 costs and benefits for alternate MCL levels of 200, 300, 500, 1000, and 2000 that was sent to the SERs is attached to this report as Appendix D. Generally, what this table shows is that the cost per cancer case avoided goes up significantly for smaller systems because they cannot benefit from economies of scale in treatment to the extent that large systems can. The table also shows that the cost per cancer case avoided goes up significantly as the MCL is tightened because more and more systems are required to install treatment. Interestingly, for a system that must install treatment, the cost of achieving a level of 300 pCi/L appears to be not much different than the cost of achieving a level of 2,000 pCi/L. The effect of ratcheting down the MCL is thus to require more and more systems to install treatment, but not to significantly change the cost per system for those that do. This is largely a function of the effectiveness of aeration in removing radon. Once installed, aeration technologies are frequently 90+ % effective in stripping radon out of water; depending upon configuration of the technology and influent radon levels.

Two Panel members suggested that one option would be for EPA to set the MCL at the same level as the AMCL. Based on an assumed water-to-air transfer factor of 10,000 to 1 and an assumed background concentration in outdoor air of 0.3 pCi/L (the NAS report will include updated estimates for these two key parameters), this would translate to an MCL of 3,000 pCi/L. These Panel members believe there would be several advantages to such an MCL. First, it would presumably show an even more favorable cost/benefit ratio than an MCL of 2,000 pCi/L, which was the highest level analyzed in the 1993 RIA. [Note that even the 2,000 pCi/L MCL has an average cost per cancer case avoided across all systems of $1.6 million, which is nearly double the estimated $0.9 million average cost per cancer cased avoided from mitigation of radon in indoor air; this number was calculated using a 7% discount rate for consistency with the drinking water estimates.] Second, an MCL at the AMCL level would eliminate the need for a multimedia mitigation component to the rule, with the attendant administrative costs that such an option would entail. Since most states already have voluntary programs to mitigate radon in indoor air, and their new multimedia mitigation programs would likely rely on the same basic set of program measures to promote mitigation, it is not clear to these Panel members that there is any advantage in developing a new set of administrative requirements to accomplish what these voluntary programs are already designed to do.

In addition, these Panel members noted that an MCL at this level would be consistent with the principle, long recognized by many in the radiation risk management community, that excessive costs should not be imposed to regulate radiation risks below natural background levels (i.e., the 0.3 pCi/L level in outdoor air), even when such background risks exceed the upper bound of 10^{-4} excess lifetime risk that EPA normally allows for chemical contaminants in drinking water. They further noted that such an MCL would also be more consistent with EPA's recommended action level of 4 pCi/L for radon in indoor air, which represents a significantly higher lifetime risk than 300 (or even 3,000) pCi/L in drinking water. EPA considered, but rejected, an action level lower than 4 pCi/L for the indoor air program. These Panel members noted that according to EPA’s analysis, action levels of 2 or 3 pCi/L could have achieved additional risk reduction at a lower cost per cancer case avoided than a drinking water standard set at 300 pCi/L.

These Panel members recommend that EPA give serious consideration to setting an MCL at the AMCL level, or at least at a level substantially above 300 pCi/L. In this context, they note the following excerpt from a July 1993 Science Advisory Board (SAB) letter based on SAB's review of the 1991 radon in drinking water proposal, "With regard to water, as one option the Agency could promulgate a standard of 300pCi/L as has been proposed. However, in doing so it must be recognized that this involves selecting a risk reduction strategy for radon that is the most costly in terms of costs per cancer death avoided; i.e., more than four times the cost of cancer risk avoidance for airborne radon indoors. Alternatively, as another option a standard might be set at some higher level such as 1000 to 3000 pCi/L to initiate mitigation of the highest potential risks. For example, setting a water standard at 3000 pCi/L would result in water contributing no more radon to indoor air than is present in outdoor air. (Keep in mind that the radon in outdoor air arises by natural processes from soil gas and there is no way to alter the outdoor radon levels.)"

Under the statute, EPA must set the MCL as close to the MCLG as feasible (taking cost in consideration) unless it determines that the benefits of an MCL set at the feasible level do not justify its costs. In this case, EPA can set an MCL above the feasible level that maximizes health risk reduction benefits at a cost that is justified by the benefits. Two Panel members believe that the benefits of an MCL set below the AMCL level may not justify its costs, given the apparently much lower costs of avoiding cancer cases through mitigation of radon in indoor air, and recommend that EPA look closely at this question.

The EPA Panel members do not support this recommendation. They are concerned that setting the MCL at the AMCL level would effectively undermine Congressional intent with respect to the flexibility provided under this portion of the statute by the AMCL/multi-media mitigation program alternative. EPA notes that Congress could have, by statute, chosen to tie the *MCL* to the ambient outdoor air level (i.e., in the same manner as the AMCL), but chose *not* to do so. Rather, Congress left it to EPA to determine the MCL in accordance with the statutory framework discussed above.

Further, the EPA Panel members do not agree that the multi-media mitigation programs provided as an alternative under the statute amount to only a "new set of administrative requirements" that would be largely ineffective beyond existing programs. Rather, EPA believes that Congress was aware of existing state programs when it decided that more effort was necessary. The SDWA explicitly requires states to "develop and submit" a MMM program in order to adopt the AMCL, if EPA promulgates a lower MCL. EPA believes that this indicates a belief by Congress that State MMM programs need to go beyond existing State programs. When Congress presumed that an existing program might be enough, as in the operator certification requirements, it said so very clearly in the law. However, EPA would agree that currently effective state radon reduction programs would likely only need a relatively minimal additional incremental effort under the multi-media mitigation guidelines, as compared with a state currently doing little under the voluntary program

Regarding the excerpt from the SAB letter quoted above, the EPA panel members believe that it is important to recognize that the SAB discussion was written before existence of AMCL/MCL alternative and that their fundamental concerns are addressed in the construct of the 1996 SDWA amendments, which provide for an alternative MCL and a multi-media mitigation program.

The EPA Panel members believe that the SDWA acknowledged the need to balance addressing radon in water and radon in indoor air risks by making the AMCL and multimedia mitigation program option available to states and public water systems. The 4 pCi/L action level is voluntary and is not determinative in the Agency's risk management decision to regulate radon in drinking water. EPA will be considering cost and benefit in setting the MCL, as provided in the SDWA.

9.4.3 Radon Risk to Smokers

The Panel discussed the issue of whether or not the fact that radon risk may be significantly greater for smokers than for non-smokers is relevant to the standard setting process. On the one hand, radon is a naturally occurring contaminant (rather than a pollutant), and questions have been raised about the extent to which non-smoking water system customers should be responsible for reducing the higher risk smokers face as a result of a voluntary life style choice. On the other hand, smokers are water system customers too, and also entitled to protection from harmful contaminants in their drinking water. It is not clear how separate consideration of the increased risk to smokers, or consideration of the risk only to non-smokers, would fit into the statutory framework of the SDWA. Panel members agree that the significance of this issue will become clearer once the NAS estimates for incremental risks to smokers and non-smokers are available. EPA will provide analysis on risks to smokers and non-smokers separately, as well as together, in the HRRCA, in order to inform public consideration of this issue.

9.4.4 Phased-In Compliance

The Panel notes SER comments that phased-in compliance would ease the financial burden on small systems. Under SDWA, the effective date of the regulation is three years after promulgation. The Panel notes that the 4.5 years allowed for compliance with the AMCL if a state or PWS implements a multi-media mitigation program would substantially address this concern; however, the Panel encourages EPA to consider options for phased-in compliance with the MCL.

9.4.5 Multi-media Mitigation Program Guidelines

The Panel discussed several issues related specifically to development of the multi-media mitigation (MMM) program guidelines required under the radon provision in SDWA if EPA promulgates an alternative maximum contaminant level (AMCL). There was agreement among the Panel members on several general principles that EPA should consider in the development of the guidelines. These are:

1. That the guidelines should be “user-friendly”, that is, straight-forward and simple to understand and use by both States and by public water systems (PWSs).

2. That the guidelines should provide a viable and realistic alternative to meeting the MCL, both for states and for PWSs, including small systems. It is especially important that this alternative be viewed as viable by states, since adoption of a MMM program by a state will preclude the need of PWSs within that state to develop individual programs. At the same time, for PWSs in states that don't adopt statewide programs, the guidelines should provide for the development of individual programs that rely on measures that are generally within the legal authority and technical capacity of PWSs to implement.

3. That the guidelines should provide flexibility to States and PWSs in satisfying the statutory requirement that the health risk reduction benefits expected to be achieved by the program be equal to or greater than the health risk reduction benefits that would result from compliance with the MCL. In particular, states with existing programs should be given some "credit" for some risk reduction strategies already in place that continue to achieve prospective reductions. The statutory language is not explicit regarding where, in a State, such benefits must be attained; however various Executive Orders require that equity issues must be considered.

4. That provision of information to the public is an important element of any program designed to achieve health risk reduction benefits through the mitigation of radon in indoor air, given that such a program will necessarily rely, to some extent, on voluntary actions by the public.

5. That equity is an important consideration in the design of a MMM program, given the fact that the households which benefit from reductions of radon in indoor air will not necessarily be the same households that experience continued exposure to radon levels in drinking water above the MCL. In this context, the Panel believes that an important component of equity is equal opportunity for households to make informed choices, and equitable access by households to any resources made available by a state or water system to identify or implement those choices. The Panel does not believe that equity necessarily requires that all households make the same choices or achieve the same level of risk reduction. The Panel further believes that this understanding of equity is implied in the concept of MMM as framed by Congress when it provided for the development of a MMM program and compliance with the AMCL as an alternative to compliance with the MCL.

Within these broad areas of agreement, there were some specific issues where consensus was not reached. These are discussed below.

Several SER commenters expressed concern about the viability for small systems of implementing a MMM program if the state does not implement one on a statewide basis. One stated, for example, that such a program would "...probably be beyond the capability of most small towns without the addition of qualified personnel--an expense which most can't afford. Rural water systems, along with privates, will be denied use of any Alternate MCL since they lack any authority over indoor air." One SER suggested that EPA could address this concern by providing "model or example programs" to suggest how one “would work.” Another SER was interested in an "easier avenue...for utilizing the AMCL" specifically for small systems. Another stated that the role of a MMM program should be to educate the public, and concluded that, "Those who want to protect themselves will and those who don't will not."

The Panel discussed the pros and cons of developing a model program for small systems. Two Panel members supported this approach as a means of ensuring that compliance with the AMCL would be a viable option for small systems in states which do not adopt the AMCL statewide. These Panel members suggested that such a model program should be based primarily on providing information to home owners about radon risk from indoor air and ways to mitigate it. This could include providing radon test kits and "radon audits" similar to the energy audits that are currently offered to individual homeowners by energy utilities. The other Panel members, while recognizing the need for the MMM guidelines to be flexible enough to accommodate the development of programs by both states and individual systems (where needed), did not believe that a model program specifically for small systems was the best way to address this need. They pointed out that such a "one size fits all" approach for small systems could limit their flexibility, particularly in designing a MMM plan based on the level of risk reduction needed to achieve equal or greater risk reduction than would have been achieved by compliance with the MCL. A “one size fits all” approach would require systems with a minimum problem to implement a plan with the same level of effort as a system with a much more substantial problem. This approach could be construed as unfair. They also believed that the primary purpose of the guidelines should be to facilitate the development of viable MMM programs, including credible reductions in radon risk from exposure to indoor air, by states, and were concerned that inclusion of a model program specifically for small systems might undermine that purpose. While the Panel did not reach consensus on this issue, all Panel members agreed that the guidelines should facilitate development of credible programs by both states and water systems (including small systems), and recommended that EPA consider the best way to accomplish this.

Another issue on which the Panel did not reach consensus was the meaning of the statutory requirement for a MMM program to achieve "health risk reduction benefits" equal to or greater than the health risk reduction benefits that would be achieved by compliance with the MCL. EPA’s interpretation of the phrase "health risk reduction benefits" is synonymous with "health risk reduction" and refers to the actual risk reduction achieved through reduced exposure to radon in indoor air. While provision of information to homeowners is an important element in achieving such risk reduction, under this interpretation, the provision of information itself would not constitute a "health risk reduction benefit" if it did not result in actual mitigation of risk. The other Panel members suggested an alternative interpretation which would attribute some "health risk reduction benefit" to the provision of information itself, because it would support homeowners in making informed choices about what level of risk reduction, and at what cost, was appropriate for them and their families given their particular health concerns and financial constraints. Basing risk reduction strategies on such informed choice by homeowners would help ensure that risk reduction accrues to those who value it the most, and who thus derive the greatest "benefit" from it. The Panel did not agree on this point. The Panel did agree that provision of information is an important component of any risk reduction strategy. EPA is currently considering the extent to which the provision of information should "count" in the approval of a MMM program.

The Panel notes that reducing radon in air is typically more cost-effective than reducing radon in water. Thus, health risk reductions can often be achieved at lower cost by radon in air reduction measures. Further, the Panel recognizes that an information component of a multi-media mitigation strategy could play an important role in helping promote such cost effective health risk reduction measures.

The Panel also discussed the issue of the appropriate baseline against which to measure health risk reduction benefits achieved by a MMM program. For states which already have effective voluntary programs, how much "credit" should they get for health risk reduction benefits currently being produced, or expected to be produced in the future, by these programs? One SER commenter indicated a concern that "small systems in states that have a pre-existing radon remediation program will be penalized by the use of a benchmark based on current levels of radon reduction," and suggested that, "States, or other entities, should be rewarded, rather than punished, for having had a strong program for radon risk reduction in the past."

Some Panel members questioned the premise that states with strong existing programs (or systems in those states) would be "penalized" by a requirement to achieve additional health risk reductions under the MMM program. They pointed to the synergistic effect between various types of program measures and suggested that it may in fact be easier, not harder, for states with strong existing programs to achieve further reductions. They also pointed to the language in SDWA requiring states to develop and submit MMM programs as signifying Congress' intent that new health risk reduction benefits need to be achieved. Other Panel members shared the SER's concern that one state may be required to impose stricter (and more costly) measures than another to achieve the same incremental risk reductions merely because it has done a better job of reducing radon risk in the past. These Panel members suggested that states which already have measures in place sufficient to produce the level of health risk reduction benefits required by the statute should not be required to implement additional measures. All Panel members agreed, however, that the MMM program, whether it includes elements of the state's pre-existing program or not, must be sufficient to produce the required level of health risk reduction benefits in the future; past benefits should not be counted toward program approval. The Panel further agreed that some "credit" toward program approval should be given for some existing measures that are incorporated into the MMM program. EPA is currently considering how to credit such measures in program approval.

The Panel also discussed whether measures targeted specifically at smokers should play any role in a MMM program, given the likelihood that smokers are at considerably greater health risk from radon exposure than non-smokers. Section 1412(b)(13)(G) of the SDWA specifically refers to the MMM program alternative as a "program to mitigate radon levels in indoor air" which suggests that measures designed only to reduce smoking, without addressing radon exposure, would not qualify. At the same time, in recognition of the particularly high risk to smokers, the Panel agreed that outreach measures designed to promote radon reduction in indoor air that were targeted specifically toward smokers should qualify as an approvable element of a MMM program.

Finally, one SER commenter raised a concern with the legal consequences to a small system adopting the AMCL of "not meeting a known standard of safety [i.e., the MCL]." The Panel notes that such a system would be in full compliance with the legal requirements of the SDWA, provided that either the state or the system had an approved MMM program. The issue of whether such a system would be vulnerable to a civil suit by a consumer who believed that water provided by the system had caused some adverse health effect is beyond the scope of the Panel process. However, the Panel believes that the fact that Congress specifically provided for adoption of the alternative MCL under conditions which it believed would be appropriately protective of public health could certainly constitute an element in the defense by a system against such a suit.

9.5 Other Comments

9.5.1 Risk Communication

Some SERs expressed concerns that communication with customers about the risks of radon in drinking water, and especially the relative risks of radon in drinking water and in air, will be very difficult. The Panel acknowledges that radon risk communication presents a significant challenge, particularly with the potential for a less stringent alternative MCL. The Panel recommends that EPA explore options for providing technical assistance to small entities to clearly communicate the risks from radon in drinking water and indoor air, the rationale supporting the regulation, and actions consumers can take to reduce their risks.

10. REFERENCES

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